

Idaho State EMS Physician Commission Requests for Device and Medication Approval

Devices that require FDA-approval shall be presented to the Idaho EMS Physician Commission (EMSPC) for review and approval prior to the device's use by an Idaho-licensed EMS agency. In addition, all medications must be presented for review and approval prior to its use by an Idaho-licensed EMS agency. Such approval shall not constitute an endorsement of said device or medication. Instead, EMSPC approval serves as an acknowledgement that the device or medication has been reviewed and found to be potentially useful in the provision of out-of-hospital care.

Criteria for submission:

- 1. The EMSPC office must receive all required information at least 30 days prior to an EMSPC meeting. Incomplete requests and requests received less than 30 days in advance will be deferred to the next EMSPC meeting. Requests that remain incomplete less then 30 days prior to the next EMSPC meeting will be discarded and re-application must be made.
- 2. A request must be sponsored by an EMS Medical Director or EMSPC Commissioner.
- 3. A request must include the following information.
 - a. For devices, documentation of FDA-approval.
 - b. Designation as either a "new" device/medication or as a device/medication that is "similar" or "equivalent" to one already approved by the EMSPC. If "similar" or "equivalent", identify the previously approved device/medication.
 - c. Clinical evidence and published research that demonstrates the benefit of the device/medication and its safe and appropriate use by EMS providers.

- 4. A request must address the following questions.
 - a. Where does the device/medication fit in current scope of practice for Idaho EMS?
 - b. Which level of provider is this device/medication intended?
 - c. What is the intended benefit by adding the device/medication to the scope of practice?
 - d. What is the anticipated frequency of use?
 - e. What are the potential risks of improper use of the device/medication?
 - f. What are the cognitive and psychomotor skills needed in order to use this device/medication?
 - g. What is the training time required to become proficient in the use of the device/medication?
 - h. What type of equipment is needed to initiate and provide training?
 - i. Who can provide the necessary training?
 - j. What are the anticipated costs associated with implementation of this device/medication?
 - k. What is the anticipated cost per use?

EMSPC Actions:

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All information required is present with related documentation?	
YESNO	
Device/medication falls within the current scope of practice at level requested at least equivalent to current products available?	and is
YESNO	
This device/medication does not fall within current scope of practice?	
YESNO	
Device/medication is approved for use in the State of Idaho?	
YESNO	